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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/800,914

03/16/2004

Nobuyoshi Karashima

ABE-022

9622

20374 7590 08/22/2008

KUBOVCIK & KUBOVCIK

SUITE 1105

1215 SOUTH CLARK STREET

ARLINGTON, VA 22202

EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

08/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/800,914	<b>Applicant(s)</b> KARASHIMA, NOBUYOSHI	
	<b>Examiner</b> QUYNH-NHU H. VU	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 9 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3763

## DETAILED ACTION

### *Response to Amendment*

Amendment and Request for Continued Examination (RCE) filed on 6/13/08 has been entered.

Claims 9 and 12 are present for examination.

Claims 1-8, 10-11 and 13 are cancelled.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ragarude (JP 2001-293016, cited from IDS and Applicant also admitted Prior Art, on pages 1-4 of Specification of current application) in view of Tapper (US 6,600,950), Ishikawa et al. (US 4,149,533) and Goble et al. (US 5,944,715) or Fischer (US 7,040,893).

Ragarude or AAPA discloses, (in Specification, on pages 1-4), a conventional iontophoresis-based medical device for sterilizing and treating a tooth infected with a pathogenic organism by iontophoresis is known. The conventional iontophoresis medical device was provided with an electric circuit having a voltage generator and a current supplied application apparatus (such as a hand piece), a positive electrode section and negative electrode section; wherein the positive electrode section was provided needle-shaped and deeply inserted into a tooth duct and the negative electrode section was directly attached to a part of a patient body (such as oral skin, wrist, or patient can grasp in a hand...). The negative electrode/terminal is formed by the metal probes with carried out the form of the needle (see para [0005 of Ragarude]).

Art Unit: 3763

The method further comprising: contacting an oral lesion in the body tissue with a drug solution retained by a positive electrode section and it is necessary to discontinue treatment to apply the drug solution section several times (pg 3, lines 1-9 of the Spec); contacting a body tissue in the vicinity of the lesion with a second solution retained by a negative electrode section (pg 3, line 10+) to provide a closed electric circuit between these electrode section and the lesion (page 2, lines 7-16). Ragarude further discloses a treatment obtaining within as short a time as possible (see abstract of Ragarude); a current of 40  $\mu$ A or lower (such as 5  $\mu$ A is maximum, see para [0018 of Ragarude]

Ragarude or AAPA in the Specification does not clearly disclose that a conducting with current for 8 to 30 seconds; wherein the drug solution (in positive electrode) in form of a brush and containing an amphoteric surface active agent as a main ingredient; and the second solution retained in form of a sponge and containing a sodium chloride solution having a concentration of 1 to 3%.

Similarly, Tapper discloses a method and apparatus for applying iontophoresis treatment to a biological subject wherein electrical treatment current between a pair of electrodes. Tapper further discloses that the drug solution (in positive or active electrode) containing amphoteric surface active agent to enhance the electrical conductivity, permeability and penetration at the site (col. 6, lines 42-51, col. 13, lines 59-63). Tapper further discloses that the positive/active electrode is a "carrier drug" (reservoir), (col. 11, lines 23-41, col. 14, lines 48-52).

Ishikawa discloses a device and method for iontophoresis comprising: a tooth is used as an anode (positive ion, positive charge), an aqueous salt solution of sodium fluoride (NaF) is negative ion (col. 3, lines 55-63 and immersed in a sponge (Figs. 8-10, and col. 9, lines 21-25).

It is well known in the art to recognize that the salt sodium fluoride or sodium chloride are ionic salts (see Specification page 2 or Sacripante et al. (US 5,601,389) one of example to prove that NaF and NaCl are ionic salts.

Therefore, it would have been obvious to a person of ordinary skill in the art to try or substitute the sodium chloride (NaCl) salt instead of sodium fluoride (NaF) salt, as a person with ordinary skill has good reason to pursue the known options within his/her technical grasp. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to try the sodium

Art Unit: 3763

chloride (NaCl) solution, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

Goble discloses an electrically instrument for the treating tissue in cavities of the body. As noted that it can be used in side the mouth also. The device comprising a pair of electrodes (an active/positive electrode 14 and a return/negative electrode 18); wherein the active/positive electrode 14 in form of brush to contacts the tissue to be treated (col. 2, lines 57-65, col. 9, lines 55-63). Furthermore, it is well-known in the dental delivery tool to provide the brush for cleaning during a procedure.

Fischer suggests that a dental delivery tool with the step of brushing or cleaning with brush during a procedure (see abstract

Regarding about the value of conducting current of 0.2 to 0.5  $\mu$ A into 8 to 30 seconds and the concentration of sodium chloride of 1 to 3%. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the conducting time between 8-30 seconds, since it has been held that where in the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

It has been that a recitation "for 8 to 30 seconds" with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed from a prior art satisfying the claimed method or structural limitations. *Ex Parte Masham*, 2 USPQ F. 2d 1647 (1987).

Conclusion, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Ragarude/AAPA with an amphoteric as taught by Tapper to enhance the electrical conductivity, permeability and penetration at the treatment site. One skill in the art would recognize that providing a brush in the device, as taught by Goble or Fischer, for cleaning during a procedure. With the second solution contained sodium chloride retained in formed of sponge, as taught by Ishikawa, in order to enhance the electrical conductivity and able to retain the solution.

Art Unit: 3763

***Response to Arguments***

Applicant's arguments with respect to claims 9 and 12 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763